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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/601,005 03/01/96 BACKSTROM

K 06275/034001

HM22/0726

EXAMINER

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BAWA, R

ART UNIT	PAPER NUMBER
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1619

DATE MAILED:

07/26/01

BEST AVAILABLE COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/601,005	Applicant(s) Backstrom et al.
	Examiner Mr. Raj Bawa	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 23, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 46, 54-77, and 80-83 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 46, 54-77, and 80-83 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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Detailed Action

(1) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

(2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46, 54-77 and 80-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decyl glucoside and dodecyl maltoside, does not reasonably provide enablement for all alkyl saccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no basis in the specification to extrapolate these two specific alkyl saccharides to encompass the infinite number of compounds that may be classified under the broad term "alkyl saccharide."

(3) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-59, 60, 64, 77 and 80-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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1. In claims 56, 77, 80-81 employ proper Markush language (“... selected from the group consisting of ... and ...”).

2. Claim 57 is confusing because it is unclear if the formulation includes a binary propellant mixture. Similarly, it is requested that claim 58 recite the phrase “propellant mixture” instead of the term “propellant.”

3. Claim 60 contains the trademark/trade name TA-2005. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a pharmaceutical and, accordingly, the identification/description is indefinite.

4. Claim 64 is vague and confusing because the agents recited therein in the Markush group are generally not considered active agents in the drug aerosol field.

In view of the above statements, it is the Examiner’s position that the claims do not meet the threshold requirement of clarity and precision and are not in compliance for definiteness of 35 U.S.C. 112, second paragraph. Note that definiteness of the claims is important to allow

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others who wish to enter the marketplace to ascertain the boundaries of protection that are provided by the claims (*Ex parte Kristensen* 10 USPQ2d 1701, 1703).

- (4) Please update the status of the continuation data referred to in the specification.
- (5) The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- (6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703) -308-2423. The examiner can normally be reached on Tuesday through Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) -308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Bawa



RAJ BAWA, Ph.D.
PRIMARY EXAMINER